Shared Care Guidance for the Monitoring of Tocilizumab In Adult Patients

SHARED CARE GUIDELINE			
Non-proprietary name	Tocilizumab		
Dosage form and strength	Tocilizumab 20mg/ml vials for IV infusion, 162mg SC injection (Roactemra®)	BNF class	10.1.3 Drugs that suppress the rheumatic disease process > Cytokine modulators
Indication	Moderate to severe Rheumatoid arthritis		
License	Tocilizumab, (SC injection/IV infusion) in combination with MTX, is indicated for • The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX. • The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more DMARDs or TNF antagonists. Tocilizumab (SC injection) is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients. Tocilizumab (IV infusion) is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Tocilizumab (IV infusion) in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. In these patients, tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.		
Eligibility criteria for shared care	All patients		
Excluded patients	None		
Dosage and Administration	IV infusion 8mg/kg (occasionally 6mg/kg) every 4 weeks or 162mg SC weekly		

Specialist Responsibilities	• Initiate treatment (and continue, if responding) with Tocilizumab.
	• Request participation in a shared care arrangement from the patient's GP for monitoring.
	• Review the patient's condition and monitor response to treatment regularly where indicated.
	• Notify the patient's GP of:
	  ○ The dose and route of tocilizumab prescribed/administered
	  ○ Arrangements for monitoring / reviewing patient and frequency.
	  ○ Other relevant clinical information/drug therapy.
	  ○ Information and instructions given to the patient.
	• Communicate promptly with the GP when treatment is changed or, any results of the monitoring undertaken, and assessment of adverse events.
	• Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
	• Advise GPs on when to stop treatment (if appropriate).		

	• Report adverse events to the MHRA via Yellow Card Scheme. • Ensure that clear arrangements exist for GPs to obtain advice and support

GP Responsibilities	• Contact specialist team to confirm he/she is happy to accept the shared care arrangement.
	• Neutrophils – monitor at intervals advised by rheumatology team and report results
	  ○ IV therapy – usually once every 4 weeks (5 days before the next infusion)
	  ○ SC therapy – usually once every 3 months
	  ○ Or as per the schedule of monitoring for methotrexate/other concomitant DMARDs
	  ○ If neutrophils are <1 then the GP should contact the NUTH DMARD service/rheumatology nurse specialist
	• Liver enzymes (ALT/AST) - monitor as per neutrophils
	  ○ If ALT/AST rise to 3x UNL the GP should contact the NUTH DMARD service
	• Lipids – monitor every 6 months and, if raised, treat as per local guidance (FATS).
	• Notify the NUTH DMARD service/ rheumatology nurse specialist of any relevant adverse reaction or any other relevant laboratory results or other information relevant to the patient's care.
	• To seek advice from the rheumatology team there are any serious adverse reactions or other concerns.
	• Annual influenza vaccine is recommended.
	• COVID vaccination in accordance with current Department of Health Guidance for immunosuppressed people.
	• Pneumococcal vaccine is recommended.

Adverse Effects, Precautions and Contraindications	• Very common: Upper respiratory tract infections, hypercholesterolaemia • Common: Abdominal pain, mouth ulceration, gastritis, rash, headache, dizziness and hypertension. • Rare: Gastro-intestinal ulceration and perforation. • Infusion related reactions and anaphylaxis. • Raised hepatic transaminases and neutropenia. • Patients who develop a new infection while undergoing treatment with Tocilizumab should be monitored closely. Administration of Tocilizumab should be discontinued if a patient develops a serious infection i.e., one that requires antibiotic therapy. Antibiotic therapy, where indicated, must be commenced promptly and only once the course completed and the infection has resolved should therapy with tocilizumab be re-commenced. • ALL side effects should be reported to the NUTH rheumatology team
Common Drug Interactions	• Avoid concomitant use of live vaccines
Communication/Contact Details	NUTH Rheumatology dept / DMARD service for. DMARD monitoring 0191 2231156. Clinical Nurse Specialists 01912231171. On-Call Rheumatology Registrar 0191 2336161 DECT 39964

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF

Private and Confidential

Shared Care Request/Confirmation -

- Consultant to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days

		Patient details (use hospital label if preferred)	
Specialist Prescriber	……	**Name**	……
Department	……	**Address**	……
Hospital	…… ……		……
Telephone	……	**Postcode**	**M/F** ……..
		NHS or Hosp. Reg. No. ……	**DoB** ……..

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement

Drug Name – Tocilizumab Dose …… Frequency……
Indication – RA
Other info (if appropriate) ……

Signed
(Consultant/ Nurse Specialist) …… Name (print)..... Date……

To be completed by GP

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ○

or

I ACCEPT the proposed shared care arrangement with the caveats below ○

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ◉

My caveats / reason(s) for not accepting include:

……..

……..

Signed …… **Name (print)** ..... **Date** ……
(Patients GP)

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP